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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,863	11/21/2001	Ruth Meissner	Mo6761 LeA 35,018	9206

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BAYER CROPSCIENCE LP
100 BAYER ROAD
PITTSBURGH, PA 15205

EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	13

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/988,863	Applicant(s) Meissner et al.
	Examiner Joyce Tung	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 24, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 25-58* is/are pending in the application.

4a) Of the above, claim(s) *1, 25-47, and 49-58* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *48* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group VII in Paper No.11 is acknowledged. The traversal is on the ground(s) that claims 50 and 51 directed to one ore more modulators which are identified according claim 48 and therefore, these claims should be examined together. This is not found persuasive because as set forth in the Office action mailed 11/19/2002, group IX, claims 50-51 are drawn a modulator which can be nucleic acid, polypeptide, antibody and any chemical compounds and these products can be used in nucleic acid purification or protein purification. Thus, the argument has been fully considered, but not persuasive.

Therefore the requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 25-47 and 49-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups I-VI and VIII-XI, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper 11 discussed above.

Now claims 1 and 25-58 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 48 is vague and indefinite because claim 48 depends from claim 25 which is a non-elected claims. It is suggested to amend the claim to have a correct dependency. Further, it is suggested to have identification number for the nucleic acid or amino acid which encodes the phosphomevalonate kinase used in the claimed method.

In addition, in comparison step (b), it is unclear whether or not the same chemical compound is used in the comparison step(b). Clarification is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Astrazeneca et al. (WO 01/145533) in view of Levin et al. (WO 00/15809).

Astrazeneca et al. disclose the phosphomevalonate kinase (PMK) gene (ERG8) from *Candida Abicans*. The invention relates to the methods for its expression yielding PMK protein and to the assays for identifying inhibitors of the enzyme (See pg. 1, lines 5-10). The ERG8 gene has been cloned from *Candida Abicans* (See pg. 1, lines 27-30). The invention also provides a host cell adapted to the *Candida Abicans* ERG8 peptide (See pg. 10, lines 4-5). The *Candida Abicans* ERG8 enzyme may be used in biochemical assays to identify agents which modulate the activity of the enzyme (See pg. 10, lines 27 to pg. 11, lines 1-2). The method of identifying compounds that modulate, preferably inhibit, the activity of phosphomevalonate kinase (PMK), comprises, contacting a test compound with a polypeptide of the invention and determining the effect that the test compound has an effect on the activity of the polypeptide (See pg. 11, lines 6-9).

Astrazeneca et al. do not disclose that a chemical compound is contacted with a host cell comprising the nucleic acid or peptide with the biological activity of a phosphomevalonate kinase.

Levin et al. disclose that Uracil Permease activity is screened with compounds. The assay consists of growing *E.coli* uraA harboring and functionally expressing the 4788 gene in minimal medium in the presence of a minimal inhibitory concentration (See pg. 39, last paragraph to pg. 40, the first paragraph).

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Astrazeneca et al. by applying the method of Levin et al. to find a chemical compound which binds to the phosphomevalonate kinase by contacting a host cell with the chemical compound. Levin et al. disclose directly contacting the host cell in vivo with chemical compounds. So the enzyme used in the assay is without protein purification procedure and the activity of the enzyme would not be reduced by going through the protein purification procedure. Therefore, the assay method of Levin et al. would be accurate. In addition, Levin et al. did not disclose comparing the biological activity of the enzyme in the presence of a chemical compound with the biological activity of the enzyme in the absence of the chemical compound. However, comparison step involved in an assay for finding a modulator of an enzyme was routine practice in the art at the time of the instant invention. It would have been prima facie obvious to carry out the method of finding a chemical compound which binds to a polypeptide with the biological activity of a phosphomevalonate kinase.

6. The reference of Lange et al. (Proc. Natl. Aca. Sci. U.S.A., 1999, Vol. 96(24), pg.13714-13719) is made of record as reference of interest because Lange et al. disclose the characterization of phosphomevalonate kinase.

Summary

7. No claim is allowable.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J. T

August 5, 2003

ETHAN WHISENANT
PRIMARY EXAMINER